DiME deep dive

Quantifying the ROI of using digital endpoints

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

> Collaboration in the development of digital endpoints can spread both cost and risk to further increase absolute value for every organization. If going at it alone returns substantive value, think of the value we can achieve by going at it together.

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Key findings

- ✔ **Enhanced efficiency:** Digital endpoints significantly shorten trial phases and permit smaller trial enrollment sizes
- ✔ **Financial gains:** Phase 3 trials showed an increase in eNPV between $24M and $40M per indication
- ✔ **High ROI:** Returns on investment range from 4 to 6 times the cost of implementation

Quantifying the ROI of using digital endpoints

Overview

Tufts Center for the Study of Drug Development (CSDD), Digital Medicine Society (DiMe), and other industry leaders combined forces to take on research that had never been done before: Quantifying the financial costs and benefits associated with using digital endpoints. The results empower decision-makers and digital health innovators with the evidence of substantial value and return on investment (ROI) they need to invest in digital endpoints and advance clinical research.

The challenge

Digital measures provide the clinical trials community with unparalleled insights into real-life patient experiences, characterizing disease and enhancing our understanding of treatment effects. Despite this, digital endpoints have yet to be widely implemented in clinical trials.

One reason why is that our industry didn't have proof that deploying digital endpoints results in ROI. Many have theorized that, due to the increased volume and sensitivity, digital endpoints could result in smaller sample sizes and shorter (thus, cheaper) trials. That said, very little quantitative data exists to back up the many assumptions about the potential financial benefits of using digital endpoints.

In 2023, the Tufts CSDD and DiMe united with industry leaders at Johnson & Johnson, Roche, Genentech, UCB, Bayer, Takeda, and MindMed to address that problem head-on.

The solution

Together, they conducted **a first-of-its-kind study** quantifying the net financial impact of deploying digital endpoints in clinical trials.

First, the team downloaded information from approximately 450,000 clinical trials in ClinialTrials.Gov (as of April 14, 2023) from the AACT database and matched indications from that registry with DiMe's Library of Digital Endpoints. They only analyzed industry-involved interventional trials and interventions that were drugs, biologics, or devices.

The team supplemented this publicly-available data by running an additional industry survey on the costs of including digital endpoints in clinical trials. The survey, which gathered data on actual costs of digital endpoint development and implementation,

provided the basis for the team to evaluate whether the benefits of digital endpoints outweighed their costs.

Based on this, the team developed an expected net present value (eNPV) model of the cash flows for new drug development and commercialization to assess financial value. They also calculated a return on investment (ROI) as the ratio of the estimated increment in eNPV to the mean digital endpoint implementation cost.

The success

The study findings showcased significant cost reductions and financial benefits tied to using digital endpoints in trials, most notably:

- ✔ For phase 2 trials, the increase in eNPV varied from $2.1 million to $3.3 million, with ROIs between 30% to 48% per indication
- ✔ The net benefits were substantially higher for phase 3 trials, with the increase in eNPV varying from $24 million to $40 million, with ROIs that were four to six times the investment

These findings, and more, were published in "Assessing the Net Financial Benefits of Employing Digital Endpoints in Clinical Trials" in the Journal of Clinical and Translational Science in July 2024.

Now, decision-makers within clinical development programs have the data they need to evaluate and invest in digital endpoints as a new modality in the context of a more accessible clinical trial enterprise.

Looking ahead

This is the first data set available to date - and we must continue to study how digital endpoints are transforming clinical research to drive their adoption and scale. Further research should be conducted to:

- Identify the additional costs and benefits to evaluate the total absolute value that developing and deploying digital endpoints brings to the drug development industry
- Establish methods for monitoring and benchmarking the growth of digital endpoints across the industry to support leaders in assessing the maturity of their digital measurement capabilities.

- Assess ROI on a case-by-case basis to lower the barrier for decision-makers to support the implementation of digital endpoints in their clinical trials.

DiMe's next project, Building the Business Case for Digital Endpoints, will tackle these important questions and more. In parallel, Tufts CSDD is building upon its earlier work on "Innovation in the pharmaceutical industry: New estimates of R&D costs."

Learn more about DiMe's frameworks and resources

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